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EXAMINER

BEISNER, WILLIAM H

ART UNIT PAPER NUMBER

1744

DATE MAILED: 10/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/890,855

Applicant(s)

PORTER ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 Oct. 2001 (Pre.Amnd.).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **DETAILED ACTION**

#### ***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### ***Information Disclosure Statement***

2. The information disclosure statement filed 31 Oct. 2001 has been considered and made of record.

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 6, 7, 9, 11-13, 17-24, 35 and 37-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Holbrook (US 5,403,741).

With respect to claim 1, the reference of Holbrook discloses a method of culturing and/or subculturing an organism that includes providing a first vessel (41) containing a first body of growth supporting material (42) and causing the organism to grow in said material in said first vessel (41) towards a first location (47); providing a second vessel (43) containing a second body of growth supporting material (48,49); and permitting the organism to grow from the body of the

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material (42) in the first vessel (41) into the body of material in the second vessel (43) through said first location (47).

With respect to claims 2 and 3, the first and second containers are connected in a sterile manner (See Figure 6).

With respect to claim 6 and 7, the organisms are caused to grow in a vertical direction from the first container into the second container and the second container is of a different length than the first container (See Figure 6).

With respect to claim 9, the reference of Holbrook discloses that the tubular member (43) can be made of a plurality of vessels forming a plurality of serially connected chambers (See Figure 11).

With respect to claim 11, the positioning of the second vessel, including a selective medium, with respect to the first vessel causes the microorganisms to grow or be trained to grow in predetermined vertical direction.

With respect to claim 12, the entire population of organisms within the first vessel is exposed to the second vessel.

With respect to claim 13, the opening of the second vessel is exposed to the medium of the first vessel.

With respect to claims 17-19, 35 and 37-41, tubular member (43) of Holbrook includes two ends (first and second locations) and contains a growth medium. The bottom end of the tubular member exposes the entire cross-section of media in the member. The tubular member is structured so as to be attached to container (41) so as to engage the growth medium in container (41).

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With respect to claim 20, the material of the tubular member is capable of being sterilized.

With respect to claim 21, the ends of the tubular housing constitute formations that are capable of cooperating with an additional structure, such as a lid or another culture device.

With respect to claims 22-24, the tubular member includes filters (47, 48) for retaining the culture medium and allowing the passage of microorganisms. The device includes retaining means for holding the filters, if not, the filters could not be maintained within the tubular member.

3. Claims 10-12 rejected under 35 U.S.C. 102(b) as being anticipated by Entis et al.(US 4,397,955).

The reference of Entis et al. discloses a process that includes providing a growth medium in culture vessel (40); growing a population of a microorganism on or in the growth medium; and sampling the population for subculture, wherein the subculturing step includes sampling across the whole population of the microorganisms using transfer material (14).

4. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Heefner et al.(US 5,231,007).

The reference of Heefner et al. discloses that pharmaceutical compositions produced by microorganisms are known in the art (See column 1, lines 10-25). Note, the patentability of a product does not depend on its method of production. If the product in the product-by-process

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claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (See MPEP 2113).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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8. Claims 4, 5, 8, 14, 26-34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holbrook (US 5,403,741).

The reference of Holbrook has been discussed above.

While the reference discloses subculturing organisms within the second container while connected to the first container, the above claims differ by reciting that the second container is removed from the first container.

The reference also discloses that it is desirable to test a sample from the second container but is silent as to how that sample is tested (See column 6, lines 30-34). However, it would have been obvious to one of ordinary skill in the art to remove the second container from the first container for the known and expected result of allowing the sample from the second container to be tested at a site remove from the connected vessels. Removing one vessel would allow other vessels to remain in contact with the first vessel while the removed vessel would be capable of being tested independent of the other vessels. Maintaining sterile conditions would have been obvious so as to maintain the integrity of the testing system by eliminating contamination that could provide erroneous results.

With respect to the production and extraction of metabolites of claim 14, the organisms cultured within the vessels inherently produce metabolites. Furthermore, it would have been obvious to one of ordinary skill in the art to extract a produced metabolite for the known and expected result of employing the metabolite as a means to confirm the type of microorganism present in the sample.

With respect to claims 26-33, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum

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components of the culture medium based merely on the specifics of the microorganism to be subcultured within the tubular member.

With respect to claim 34, employment of sterile culture medium would have been obvious for the known and expected result of maintaining the integrity of the culture system by minimizing the possibility for contamination.

With respect to claim 36, while the reference is silent as to the use of caps to seal the end of tubular member (43), the use of caps to seal the ends of the tube would have been obvious to one of ordinary skill in the art for the known and expected result of protecting the contents of the tube prior to use of the container in the culture system.

9. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Entis et al.(US 4,397,955) in view of Rudat et al.(DE 4123107).

The reference of Entis et al. has been discussed above.

While the reference discloses culturing microorganisms in a predetermined direction and sampling the entire surface of the culture device, the above claims differ by reciting that the sampled cells are cultured and a desired metabolite is extracted.

The reference of Rudat et al. discloses that it is known in the art to store populations of microorganisms that are capable of producing metabolites, such as pharmaceutical compositions (See the abstract).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the system of the primary reference of Entis et al. for transfer of the stored microorganisms as suggested by Rudat et al. so as to provide a means recognized in the art for

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ensuring that the entire population of microorganisms within the petri dish are sampled for use to make a desired product in a fermentation device. The use of microorganisms for fermentation and extraction of a desired product is notoriously well known in the art.

***Conclusion***


10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The references of Landau et al.(US 3,205,151); Barr et al.(US 4,845,038); Entis et al.(US 5,168,037) and Pineda et al.(US 5,272,086) are cited as prior art that pertains to tubular culture vessels.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

  
William H. Beisner  
Primary Examiner  
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WHB